

Attorney Docket No.: DC-0190
Inventors: Hamilton and Stanton
Serial No.: 10/089,475
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REMARKS

Claim 9 is pending in the instant application. Claim 9 has been rejected. Claim 9 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §112

Claim 9 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner suggests that the term "ΔF508 mutant" is indefinite because there is no structure associated with this term and no art accepted meaning of this term at the time the instant invention was filed. Applicants respectfully disagree.

Page 3 (lines 15-18) clearly indicates that the ΔF508 mutation is a deletion of the phenylalanine at amino acid position 508 of the CFTR protein. Accordingly, in an earnest effort to clarify the present invention and place claim 9 in better form for consideration, Applicants have amended claim 9 to indicate that the claimed genetic construct comprises a cDNA encoding a mutant human CFTR protein having a deletion of the phenylalanine at amino acid position 508 (ΔF508). Support for this amendment is found at page 3 (lines 15-18) and page 6 (lines 3-22). In light of this clarification, it is respectfully requested that this rejection be reconsidered and withdrawn.

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II. Rejection of Claims Under 35 U.S.C. §103

Claim 9 remains rejected under 35 U.S.C. §103(a) as being unpatentable over Moyer et al. ((Aug. 1999) *Am. J. Physiol.* 277(2 Pt 2):F271-6) in view of Cormack et al. ((1996) *Gene* 173:33-38) further in view of Chou et al. (1991) *J. Biol. Chem.* 266:24471-24476) for the reasons of record. In response to Applicants arguments dated June 8, 2006, the Examiner suggests that because the term Δ F508 mutant human CFTR cDNA coding region is not defined by the specification nor the claims, the CFTR-GFP of Moyer et al. meets the limitations of the claims. Applicants respectfully disagree with this rejection.

As discussed *supra*, Applicants have amended the claims to clarify that the claimed genetic construct comprises a cDNA encoding a mutant human CFTR protein having a deletion of the phenylalanine at amino acid position 508 (Δ F508). Nowhere in the teachings of Moyer et al. is there a teaching or suggestion to use a genetic construct encoding Δ F508 CFTR-GFP. Moreover, there is no teaching or suggestion to modify Moyer et al. to employ a genetic construct encoding Δ F508 CFTR-GFP to identify agents which increase functional cell surface expression of a Δ F508 mutant CFTR protein. In so far as Cormack et al. teach mutant GFP and Chou et al. teach transcriptional regulatory elements of CFTR, these references fail to overcome the deficiencies in the teachings of Moyer et al.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify

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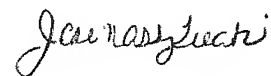
the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2142.

In so far as Moyer et al., Cormack et al. and Chou et al. fail to teach or suggest the use of a cDNA encoding a $\Delta F508$ mutant human CFTR these references cannot be held to make the present invention obvious. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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